

### REMARKS

Claims 1 to 18 are pending. Reconsideration of the application is requested.

An Appeal Brief (amended) was filed by Applicants on April 15, 2008. This Office Action, in view of the Appeal Brief, reopened prosecution to add a rejection under 35 USC § 112 and an objection to the drawings.

### § 112 Rejection

Claims 1, 8, 9, 11, 12, and 16 are rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement

The Patent Office asserts that the specification as originally filed does not include support for a solid (not hollow) microneedle tip.

The Applicants respectfully submit that the Patent Office has not shown a basis for its assertion that solid (not hollow) microneedle tips are taught in the present application. Indeed, the specification as originally filed is replete with descriptions that one of ordinary skill in the art would understand to clearly teach a microneedle that "is tapered from the base to a solid flat tip distal from the base" as claimed.

For example, page 7, lines 17 to 21, in referencing Figures 1 and 2, indicates that the "microneedles 30 each include a base 34 proximate the substrate surface 22 and a **top surface 32** distal from the base 34." Emphasis added. It is wholly unclear to the Applicants what construction of the term "top surface" as used in this context would imply that a solid microneedle is not clearly contemplated.

Further, the same page goes on to state that the described microneedles "are truncated pyramids including a **top surface 32** that may preferably be **flat**." Page 7, lines 26 to 27. Emphasis added. Again, the specification does not describe an opening, but rather a *flat surface*.

Still further, and importantly, the same passage in the specification describes the "top surface 32 may be located in a plane that is parallel to the base 34 of the microneedle 30 (in which case the microneedle 30 can be identified as a **frustum** of a pyramid)." The American Heritage Dictionary, Fourth Edition, 2000, defines frustum as the "part of a **solid**, such as a cone or pyramid, between two parallel planes cutting the **solid**, especially the section between the base and a plane parallel to the base." Emphasis added. Yet again, the clear meaning of the language

used throughout the specification is that the microneedle is indeed "tapered from the base to a solid flat tip distal from the base" as claimed.

In summary, Applicants submit that the rejection of claims 1, 8, 9, 11, 12 and 16 under 35 USC § 112, first paragraph, is inappropriate, and that the rejection should be withdrawn.

### **Objection to the Drawings**

The Patent Office objects to the drawings under 37 CFR 1.83(a), asserting that the solid (i.e., not hollow) tip must be shown in the drawings or the feature must be cancelled from the claims.

Again here, the Applicants respectfully submit that the objection is without basis. Figure 1 clearly depicts top surface 32 as a continuous solid surface. Figure 2 shows a cross section of top surface 32, again, without the feature of an opening or any hollow portions. The same holds for Figure 4. The Figures, coupled with the portions of the specification that describe those Figures (including at least those portions discussed above), obviate the objection.

In summary, Applicants submit that the objection to the drawings under 37 CFR § 1.83(a) is inappropriate and should be withdrawn.

### **§ 102 Rejections**

Claims 1 to 18 are rejected under 35 USC § 102(e) as being anticipated by Sherman et al (U.S. 2002/0020688).

The Patent Office offers a strained interpretation of the terms flat and solid, in order to formulate a rejection of the claims over Sherman. First, the Patent Office asserts that flat means pointed. It is incumbent upon the Patent Office, in asserting a rejection, to construe the terms of the claims. Even giving the term "flat" its broadest possible meaning, the Patent Office assertions are not supportable. The Patent Office asserts, in essence, that flat includes not flat. There is no clearer example of something that is not flat than a structure that comes to a sharp point. Yet the Patent Office asserts that it is reasonable to include such structures in the definition of having a flat tip, as claimed. It is unclear what the Patent Office would consider to be outside the scope of the term flat in its construction.

Further, the Patent Office asserts that a solid flat tip having a surface area of 20 square micrometers to 250 square micrometers encompasses structures having a hollow surface with an opening of between 20 and 100 square micrometers. Again here, it is the solid flat tip that comprises a surface area of 20 square micrometers or more and 250 square micrometers or less, as claimed. The Patent Office, if credence is to be given to its all-encompassing definition of flat, still is only asserting that the perimeter of the pointed hollow needles of Sherman are "flat". Thus, it is unclear how the cross sectional area of the hollow channel in the tip of Sherman is related in any way to the surface area of the tip. It strains credulity for the Patent Office to assert that "surface area" applies to something that has no surface. The fact that a cross section of the opening described in Sherman may or may not fall within the range of surface areas for the solid flat tip as claimed is inapposite.

Finally, as is clear from the above discussion, but bears addressing separately, the Patent Office position is internally inconsistent. That is, the Patent Office, in order to justify its assertion that the tip of Sherman is solid and flat, points to the perimeter of the hollow needle described in Sherman. The Patent Office then points to the cross-sectional area of the opening of the hollow needle in Sherman to assert that the surface area limitation is met. It is clearly claimed, though, that it is the solid flat tip that comprises a surface area measured in a plane aligned with the base of 20 square micrometers or more and 250 square micrometers or less. That is, the assertion that the opening, not the base, has a cross sectional area of 20 to 100 microns is completely unrelated to the whether the asserted "solid flat tip" of Sherman (which Applicants contend is neither solid nor flat), comprises a surface area as claimed.

The rejection of claims 1 to 18 under 35 USC § 102(e) as being anticipated by Sherman is inappropriate and should be withdrawn.

**Conclusion**

In view of the above, it is submitted that the application is in condition for allowance. Examination and reconsideration of the application is requested.

Respectfully submitted,

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